K072681

LifeScience PLUS, Inc.
P.O. BOX 60783
Palo Alto, CA 94306

510(k) Summary

NOV - 2 2007

1. Submitter/Owner: LifeScience PLUS, Inc. P.O. BOX 60783
   473 Sapena Court, Suite #7 Palo Alto, CA 94306
   Santa Clara, CA 95054
   (Tel) 1-650-565-8172
   (Toll free) 1-877-587-5433
   (fax) 1-440-445-2752

2. Contact Person: Vicky Feng

3. Date: September 11, 2007

4. Device Name
   Trade Name: BloodSTOP and BloodSTOP iX Hemostatic Gauze
   Common Name: Hemostatic wound dressing
   Product Code: FRO, unclassified

5. Predicate Device: Seal-On Hemostatic Powder Spray, K010933

6. Device Description and Intended Use:

BloodSTOP and BloodSTOP iX Hemostatic Gauze are made from regenerated cotton cellulose, chemically treated to become water-soluble. When contacting blood and exudates, they expand into clear gel, thereby adhering and creating pressure to seal the wound.

Intended Use: Non-absorbable hemostatic gauze for emergency and therapeutic use in the control of bleeding from the skin and other surface wounds where temporary control of bleeding is required.

7. Substantial Equivalence:

BloodSTOP and BloodSTOP iX Hemostatic Gauze are used to control bleeding, as is the predicate device. They are of similar composition as the predicate device, being made from chemically treated plant-source cellulose. They are similar in principle of operation in that both transform into a gel, covering and protecting the wound while hemostasis is achieved. They differ in presentation and method of application, as the predicate is a microdispersed cellulose in aerosol form. Animal studies included in this submission show that BloodSTOP and BloodSTOP iX are equivalent or faster than the predicate Seal-On Powder Spray in time to hemostasis. BloodSTOP and BloodSTOP iX are biocompatible, as demonstrated by test results included in this premarket submission. BloodSTOP and BloodSTOP iX Hemostatic Gauze are substantially equivalent to the cited predicate device in intended use and technological characteristics. Differences in technological characteristics do not raise new issues of safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

LifeScience PLUS, Inc.
% Ms. Audrey Vitale
22 Stony Hill Drive
Mystic, Connecticut 06355

NOV - 2 2007

Re: K072681
Trade/Device Name: BloodSTOP and BloodSTOP iX Hemostatic Gauze
Regulatory Class: Unclassified
Product Code: FRO
Dated: September 19, 2007
Received: September 21, 2007

Dear Ms. Vitale:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3. Indications for Use

510(k) Number (if known): K072681

Device Name: BloodSTOP and BloodSTOP iX Hemostatic Gauze

Indications For Use:

Non-absorbable hemostatic gauze for emergency and therapeutic use in the control of bleeding from the skin and other surface wounds where temporary control of bleeding is required.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K072681